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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
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EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/033,325

Applicant(s)

POULOSE ET AL.

Examin r

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: .

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DETAILED ACTION*Priority*

Applicants' priority documents, U.S. patent applications serial Nos. 08/956,323, 08/956,324, and 08/956,564, all filed October 23, 1997, are considered to provide the disclosures of the positions designated as sites for amino acid substitutions set forth in Table 1, pages 4-22 herein, with the priority date of October 23, 1997. The claim to priority is however, incomplete, for it fails to cite the intervening application serial No. 09/178,155, now U.S. Patent No. 6,312,936, which shares copendency with the instant application, which Applicant identifies in the Declaration of Inventorship filed with this application on November 2, 2001, and of which the instant application is a continuation.

Information Disclosure Statement

Applicants' submission of an Information Disclosure Statement, Paper No. 7 filed November 7, 2001, is hereby acknowledged. It is noted that every one of the documents cited on the second page of the PTO Form-1449 supplied with the Information Disclosure Statement is a duplicate citation of a document first cited on the first page of the PTO Form-1449 supplied with the Information Disclosure Statement, thus all citations are lined-through. It is also noted that the first publication in the "OTHER DOCUMENTS" section of the first page of the Information Disclosure Statement's PTO Form-1449 is incomplete, thus the citation is also lined-through. U.S. Patents made of record by the examiner in the prosecutions of Applicant's intervening patent applications sharing priority documents with the instant application, but not cited by Applicant on either of the PTO Forms-1449, are made of record in the instant application on the accompanying PTO-Form 892.

Specification

Applicants' preliminary Amendment A filed November 2, 2001, has been entered, providing the sequence listing in printed form, revising page 1 of the specification to

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correct the filing dates indicated for Applicants' three U.S. priority applications, and amending the descriptions of Figures 1A, 1B, 3A and 3B at page 23 of the specification. The amendment is, however, incomplete and must be further amended in response to this communication to cite the intervening application serial No. 09/178,155, now U.S. Patent No. 6,312,936, which shares copendency with the instant application, which Applicant identifies in the Declaration of Inventorship filed with this application on November 2, 2001, and of which the instant application is a continuation. As was the case in the earlier prosecution of the intervening application serial No. 09/178,155, now U.S. Patent No. 6,312,936, Applicant is not required to restate the contents of each of Tables 1-3 within the text of claims 10-12 because the Tables of the specification are the best and clearest means of describing Applicants' intended structural alterations in multiply-substituted subtilisin proteases where claim 1 requires that indicated positions for substitution be identified by correspondence with the amino acid sequence of subtilisin BPN', the secreted, mature, serine protease of *Bacillus amyloliquefaciens*. There is no need that claim 1 recite SEQ ID NO:3 herein as the sequence with which positions for substitution are identified by correspondence because the sequence is well-known in the art as the benchmark subtilisin amino acid sequence for determining such correspondence, as demonstrated by the prior art cited in Applicant's Information Disclosure Statement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered

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attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, and 10-12 are rejected under the judicially created doctrine of double patenting over claims 1-26 of U.S. Patent No. 6,312,628 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 1-26 of the issued patent are based on the same disclosure provided in the instant application, are entirely embraced by the subject matters of claims 1-6, 8, and 10-12 herein, and embrace in large part the subject matters of claims 1-6, 8, and 10-12 herein.

Claims 1-12 are rejected under the judicially created doctrine of double patenting over claims 1-22 of U.S. Patent No. 6,482,628 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 1-22 of the issued patent are based on the same disclosure provided in the instant application, are entirely embraced by the subject matters of claims 1-12 herein, and embrace in large part the subject matters of claims 1-12 herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are not subject to this rejection because they require no particular set of positions for amino acid substitutions, only a substitution at the subtilisin BPN' equivalent position 103 and at least one, or two, substitutions at one or more of the other designated positions and Applicant need not restate the contents of Tables 1-3 in the body of any of claims 10-12. Claims 10-12 are indefinite in reciting a format that parallels, but cannot be equivalent to, the recitation of claim 1 in requiring that the "residue positions" in every substitution set of the Tables to correspond to "positions in Table [1, 2, or 3] of *Bacillus amyloliquefaciens* subtilisin". The nature of the substitution sets in Table 3, the subject matter of claim 11 depending from claim 10, raises an inference contrary to recitations, "of *Bacillus amyloliquefaciens* subtilisin", in claims 1 and 10, as well as the nature of the amino acids at positions in substitution sets of Tables 1 and 2 prior to substitution. This is

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because amino acids at positions designated in Tables 3, 4, and 5 of the specification, and claim 11's Table 3, are evidence that Applicant does not intend that claimed substitutions be made at positions numbered by correspondence with the amino acid sequence of subtilisin BPN'. Instead, substitution sets of Table 3 indicated in claim 11, which like claim 12 depends from claim 10, do not identify amino acids present at numbered positions in the subtilisin BPN' amino sequence. Many of the indicated amino acids are instead present at numbered positions in the *Bacillus lentus* subtilisin amino acid sequence, e.g., subtilisin 309 disclosed in Åaslyng et al., made of record herewith. While A1, V4, H17, and S37 are present in both subtilisin BPN' and *B. lentus* subtilisin amino acid sequences, and T38 and N76 exist in the subtilisin BPN' sequence, the subtilisin BPN' sequence has no "S103" to be substituted by an alanine, S103A, nor does "V104" exist in the subtilisin BPN' sequence. Instead glutamine, "Q103", is present, and tryptophan, "Y104", are present in the subtilisin BPN' sequence of. Claims 10-12 are indefinite where the artisan cannot know which is the amino acid sequence to which reference should be made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 10-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Graycar et al., WO 95/10615, made of record with Applicant's Information Disclosure Statement.

Graycar et al. anticipate claims 1-3 and 10-12 in disclosing, see Table VI at pages 31 and 32, many substitution sets recited in Table 3 to which claim 11 is directed, thus also present in claims 1 and 10 from which claim 11 depends as well as present in claim 12 which depends from claim 10, wherein the substitutions occur in the amino acid sequences of both subtilisin BPN' and a *B. lentus* subtilisin where amino acids in the sequence of the

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B. lentus subtilisin differ from those present at the correspondent positions in the sequence of subtilisin BPN', yet substitutions are made for the *B. lentus* subtilisin amino acids present at the subtilisin BPN' correspondent positions. Graycar et al. also anticipate claims 4-6 in disclosing, see Figures 3-9, SEQ IDs NOs:1-5 and 11 and pages 8-34, the preparation of DNAs encoding protease variants of claim 1, expression vectors comprising such subtilisin variant-encoding DNAs and host cells transformed with the expression vectors. Graycar et al. further anticipate claim 7 in disclosing cleaning compositions comprising the multiply-substituted subtilisin variants at pages 34 and 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Claim 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over Graycar et al., discussed above above, in view of Weiner et al., U.S. Patent No. 5,589,373, made of record herewith.

The teachings of Graycar et al. discussed above are taken as before. Available as prior art under 35 U.S.C. §102(e), Weiner et al. teach, col. 3, lines 29-43, that proteases "can be used in preparing laundry detergents or in formulating animal feed". It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare animal feed compositions comprising a protease variant of Graycar et al. because Weiner et al. teach that proteases useful in preparing laundry detergents are also useful in

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preparing animal feed compositions and such an artisan at that time would have had a reasonable expectation that a protease variant of Graycar et al. would also serve as an enzymatic component of an animal feed composition just as Weiner et al. had suggested that native proteases would be useful in such compositions.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Graycar et al., discussed above, in view of Ghosh et al., U.S. Patent No. 5,677,272, made .

The teachings of Graycar et al. discussed above are taken as before. Available as prior art under 35 U.S.C. § 102(e), Ghosh et al. teach that one or more proteases may be used to formulate textile-treating compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare textile-treating compositions of Ghosh et al. comprising a protease variant of Graycar et al. because such an artisan would reasonably have expected that protease variants of Graycar et al. would be suitable for use in textile-treating compositions in view of the general teachings of Ghosh et al. who demonstrate the use of protease variants in various textile-treating compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Inquiries of a general nature, or relating to the status of this application or proceeding, should be directed to the receptionist whose telephone number is 703.308.0196.


William W. Moore
June 27, 2003